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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,084	12/05/2005	Christine Vauthier	BJS-5006-5	9469
23117 7590 11/23/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
			EXAMINER HILL, KEVIN KAI	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 11/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/533,084	<b>Applicant(s)</b> VAUTHIER ET AL.	
	<b>Examiner</b> Kevin K. Hill, Ph.D.	<b>Art Unit</b> 1633	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED November 11, 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ They raise the issue of new matter (see NOTE below);
  - (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☒ Other: See Continuation Sheet.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's Arguments

Applicant argues that:

- a) Desai does not teach that hemoglobin may be associated with the nanoparticle shell comprising a polysaccharide so as to be useful as a blood substitute;
- b) the Examiner's interpretation is hindsight;
- c) Desai is not enabling for making and/or using hemoglobin shells, as there is no teaching or working example of how this might be accomplished, nor any confirmatory tests; and
- d) the quantities of hemoglobin associated at the surface of the nanoparticle may vary greatly depending on the nature of the polysaccharide present at the nanoparticle surface, and whether the copolymer is branched or sequenced.

Applicant's argument(s) has been fully considered, but is not persuasive.

With respect to a), in response to Applicant's arguments against the references individually (Desai), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the instant case, Chauvierre et al teach the synthesis of heparin-coated poly(cyanoacrylate) nanoparticles. Desai et al disclose that hemoglobin may be present in the polymeric shell of a heparin-coated particle, thereby providing a blood substitute. It would have been obvious to one of ordinary skill in the art to modify the nanoparticle of Chauvierre et al to include a hemoprotein such as hemoglobin as taught by Desai et al with a reasonable chance of success because Desai et al teach that the biocompatible agent, that is, hemoglobin may be associated with the nanoparticle shell comprising a polysaccharide so as to be useful as a blood substitute, and the art has long recognized that heparin, being polyanionic in nature, has a high affinity for basic proteins like hemoglobin.

With respect to b), in response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case, the Examiner has used only the teachings of the prior art as the basis for the rejections.

With respect to c), when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on Applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). The fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). The court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. In the instant case, Applicant has provided no evidence that a nanoparticle of Chauvierre et al comprising hemoglobin as taught by Desai et al would not be enabled.

With respect to d), in response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., whether the copolymer is branched or sequenced) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 1-6, 8-10, 15-16 and 19 stand rejected.

Continuation of 13. Other: While the Examiner had previously (June 15, 2007) considered the references in the IDS filed April 17, 2007, a copy of the IDS with the Examiner's initials is provided as per the request filed July 24, 2007.



Q. JANICE LI, M.D.  
PRIMARY EXAMINER

